IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOSTAVAX (ZOSTER VACCINE LIVE) PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2848
THIS DOCUMENT RELATES TO:	:	
1189 Actions Listed in Appendix A to Pretrial Order No. 458	:	

MEMORANDUM IN SUPPORT OF PRETRIAL ORDER NO. 458

Bartle, J. December 6, 2022

This multidistrict litigation ("MDL") concerns Zostavax, a vaccine developed and manufactured by defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. ("Merck") to prevent the occurrence of shingles. Plaintiffs claim in 1,189 separate actions now before this court that Zostavax did not do what it was supposed to do and instead caused them to suffer from shingles or shingles-related injuries. Defendants now move to dismiss all these actions under Rule 41(b) of the Federal Rules of Civil Procedure for failure of plaintiffs to come forward with prima facie supporting evidence as called for by

Pretrial Order No. 426.[1] Fifteen plaintiffs' firms filed opposing briefs. Thirteen of these briefs were substantively identical. Each of the fifteen advanced generally the same arguments.

The court with the agreement of the parties has divided the more than 2,000 cases in this MDL into Groups A, B, and C for management purposes. Group A cases are those in which plaintiffs allege that they have suffered shingles or shingles-related injuries. Group B consists of those cases where the plaintiffs allege various other injuries as a result of Zostavax. Group C cases involve alleged hearing loss injuries. The 1,189 actions which are the subject of defendants' pending motion are part of Group A.[2]

This MDL is now over four years old. Extensive discovery has taken place. Merck has produced over 6,000,000 pages of documents related to Zostavax and made nearly

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1. Rule 41(b) provides in relevant part: "If the plaintiff fails to prosecute or comply . . . with a court order, a defendant may move to dismiss the action or any claim against it."

In this motion, defendants also sought in the alternative summary judgment under Rule 56 of the Federal Rules of Civil Procedure. By agreement of the parties, the court stayed defendants' motion to the extent they moved for summary judgment in order to permit the court to address defendants' motion to dismiss under Rule 41(b). See Pretrial Order No. 452.

2. Group A also includes some 500 cases in which plaintiffs allege they suffered from both shingles-related and non-shingles-related injuries. Those actions are not presently before the court.

40 persons available for depositions. Specific fact discovery has been completed in the five Group A bellwether cases selected for trial. Numerous expert reports were exchanged and depositions of experts conducted.

After completion of this massive discovery, Merck filed a motion in each of the five Group A bellwether cases to exclude the testimony of plaintiffs' causation expert, Dr. Mark Poznansky, under Rule 702 of the Federal Rules of Civil Procedure and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). The law requires a plaintiff's medical expert's opinion on causation to exclude any obvious alternative cause. Heller v. Shaw Indus., Inc., 167 F.3d 146, 156 (3d Cir. 1999). The court held that Dr. Poznansky had failed to make this differential diagnosis to exclude as a cause of plaintiffs' shingles a reactivated shingles (wild-type) virus already present in their bodies because of having contracted chickenpox earlier in their lives. In re Zostavax (Zoster Vaccine Live) Prod. Liab. Litig., 579 F. Supp. 3d 675, 681 (E.D. Pa. 2021). Without the required expert causation testimony to support plaintiffs' claims, the court entered summary judgment in favor of Merck in each of the five cases on December 1, 2021. Pretrial Orders Nos. 411, 413, 415, 417, 419. The plaintiffs appealed the decision in four of these cases but promptly

thought better of it and voluntarily dismissed those appeals on May 20, 2022.

It is well-known that the varicella-zoster virus ("VZV") causes both chickenpox, which typically occurs in childhood, and shingles, that is, herpes zoster, which occurs later in adulthood after a person has experienced chickenpox. The VZV remains in the body for life. It travels up nerve fibers from the skin and becomes dormant in nerve cells, called ganglia, near the spinal cord until it reactivates. When it reactivates, it travels down the nerve fibers and results in shingles. Virtually all persons over the age of 30 in the United States have had chickenpox and carry the so-called wild-type virus in their systems. Shingles manifests itself in a painful rash on various parts of the body. One out of three adults will experience shingles during his or her lifetime. Rafael Harpaz et al., Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 57 Morbidity & Mortality Wkly. Rep. 2, 9 (2008). The CDC estimates that one million new cases of shingles occur each year in the United States. Id.

Zostavax was developed to prevent shingles in adults 50 years and older and was licensed by the Food & Drug Administration in 2006. It consists of the Oka strain of the VZV, a live-attenuated virus that is a weakened form of the

natural or wild-type virus found in the body of someone who has had chickenpox. Zostavax is not designed to produce immunity by causing a mild case of shingles but rather to prevent shingles by effecting immunity before an outbreak of shingles takes place. From the beginning, Merck made it clear that Zostavax's effective rate was around 50% and waned over time. The effectiveness also declined with the age of the patient. While Merck concedes that an immunocompetent adult who receives Zostavax can develop shingles from the live-attenuated virus, Merck points to various studies that show that only one such case is known ever to have occurred. There is no evidence in the record of any other such case.

Plaintiffs, of course, have the burden of proof to establish that Zostavax caused their shingles in each individual case. In doing so, they must rule out the obvious alternative cause that the wild-type virus reactivated. On this issue Merck has presented the court with uncontradicted medical authority that a laboratory test of a person's shingles rash--specifically a polymerase chain reaction assay, otherwise known as a PCR test--is the only way to tell whether the shingles was caused by the virus strain contained in Zostavax or by the wild-virus strain from chickenpox closeted in a person's body. See, e.g., Harpaz et al., Prevention of Herpes Zoster, supra, at 1, 6. Plaintiffs concede that it cannot be determined which strain of

the virus causes shingles simply by how the rash appears. November 17, 2021 Hr'g Tr., at 43:6-11 (Doc. # 992).

Significantly, Dr. Poznansky, plaintiffs' own causation expert, has recently testified "where we're looking at causation cases, to determine whether it was vOka or wild-type VZV, you would actually need to do definitively a PCR test to do it." Likewise the attorney for over 700 plaintiffs in this MDL and for plaintiffs in a similar California proceeding against Merck involving Zostavax has candidly written: "Shingles caused by the Oka/Merck strain VZV cannot be distinguished on clinical observations from shingles caused by wild-type VZV; a PCR assay test is needed to make this determination."

On March 30, 2022, several months after entering summary judgment in favor of Merck in the Group A bellwether cases, the court granted Merck's motion for a Lone Pine order, named for Lore v. Lone Pine Corp., No. L-33606-85, 1986 WL 637507 (N.J. Super. Ct. Law Div. Nov. 18, 1986).[3] In that order, Pretrial Order No. 426, the court required all plaintiffs in the Group A cases to "serve laboratory reports or other records documenting that strain-identification testing detected vaccine-strain varicella zoster virus ('VZV') in a rash

3. A Lone Pine order is a mechanism "by which trial courts require plaintiffs to produce threshold prima facie support for their claims, such as expert reports and medical records." Hamer v. LivaNova Deutschland GmbH, 994 F.3d 173, 178 (3d Cir. 2021).

sample from the plaintiff ('Laboratory Reports')." This could not come as a surprise. In this MDL, plaintiffs have been obligated to produce various medical documentation by pretrial order. See, e.g., Pretrial Order No. 46. The court concluded its Memorandum in support of Pretrial Order No. 426 with the following:

> It is now time for plaintiffs to come forward with the Laboratory Reports or other documentation Merck requests to enable the court to weed out non-meritorious from meritorious claims and move along these . . . cases toward a final resolution. A Lone Pine management order is the only viable way that "will promote the just and efficient conduct of [these] actions. 28 U.S.C. § 1407(a)."

In re Zostavax (Zoster Vaccine Live) Prod. Liab. Litig., MDL No. 18-2848, 2022 WL 952179, at *3 (E.D. Pa. Mar. 30, 2022).

The plaintiffs were given 90 days to serve the laboratory reports or other relevant documentation.[4] No extensions were requested, and this period has now expired.

It is undisputed that not one of the 1,189 Group A plaintiffs has provided the required laboratory report or laboratory equivalent documentation. In addition, plaintiffs, who always have the burden of proof, have produced no expert report and have produced no published literature that conclude that the strain of shingles caused by the vaccine can be

4. For any new Group A case, a plaintiff must comply with Pretrial Order No. 426 within 90 days after the action is filed.

diagnosed in absence of a laboratory PCR test. Indeed plaintiffs' expert, Dr. Poznansky, as noted above, did not provide a differential diagnosis in his expert reports in the five bellwether cases and has testified more recently that a PCR test is required to make the specific cause determination. In sum, the record is undisputed that such testing is the only way to prove whether Zostavax or the wild-type virus caused a person's shingles. Otherwise, causation in any case is mere speculation. Those PCR test reports can only be prepared from an examination of existing rashes. It is in the nature of shingles that the rashes manifesting shingles disappear after a time. Because the rashes of all the plaintiffs which were allegedly caused by Zostavax ceased to exist long ago, there is no chance of any laboratory reports of the causes of the rashes ever being generated, either now or at any point in the future. Without such reports, the cases of the Group A plaintiffs will fail for want of proof.

Faced with this obvious predicament, the Group A plaintiffs simply make numerous unsupported and irrelevant pronouncements concerning specific causation in their briefs in opposition to Merck's motion to dismiss. For example, in each opposing brief (E.g., Doc. # 1092), plaintiffs state in a footnote on page 1, "Plaintiffs have the right to and can prove specific causation in their individual cases without PCR

testing. To this end, Plaintiffs have addressed such in the Appendix that has been annexed hereto as Ex. 2." Consequently, the court eagerly turned to the Appendix to see what plaintiffs' previously undisclosed proof of specific causation might be. The Appendix, on which all plaintiffs rely, states on page 1 that "Plaintiffs address the merits of their respective cases here, and, particularly, how they generally intend to prove their claims at trial given that PCR testing is inherently unreliable in proving same." Unfortunately the Appendix is not what it is billed to be. It baldly states on page 3 that "Plaintiffs argue, as supported by their experts, that, except in unique circumstances, every case of Shingles after vaccination is more likely than not caused by or contributed to by the Oka strain." Yet plaintiffs never say who those experts are, never cite to any supporting expert report, and never attempt to explain away the contrary testimony of Dr. Poznansky.

The Appendix then references "the concept of immunosenescence, or the weakening of the immune system as we age" and the existence of COVID-19. It never goes on to tell the reader how these references are relevant to prove that Zostavax, rather than the wild-type virus, caused any specific plaintiff to contract shingles.

The Appendix on page 5 states that since the court dismissed the five Group A bellwether actions for failure of

Dr. Poznansky to opine on case specific causation, "additional support for causation from the CDC has been identified by Plaintiffs which they intend to introduce at the appropriate time." The reader is then directed to footnote 6 which states, "This additional support was submitted by the plaintiffs' experts in the New Jersey state court consolidated [Zostavax] litigation, and this matter is currently being briefed by Judge Kaplan." The court looked forward to plaintiffs' revealing what this additional support might be. Again, the plaintiffs never disclosed what was behind the curtain. In addition, plaintiffs ignore the contrary testimony of Dr. Poznansky which is also before the New Jersey court. It is puzzling that it is the "appropriate time" for plaintiffs to share their allegedly critical and supportive evidence with Judge Kaplan but not with this court, particularly if plaintiffs really think that this evidence might defeat Merck's pending motion to dismiss 1,189 cases in this MDL. The court can only conclude that there is no such evidence.

Plaintiffs then argue on page 6 of the Appendix that the court should "accept Plaintiffs' experts' opinions that every case of Shingles following vaccination was more likely than not caused by the vaccine . . . . In other words, Plaintiffs' experts opine that . . . [a] 65-year-old would have up to a 0% chance of naturally developing Shingles after

Zostavax." Again, plaintiffs never identify their experts or supply their opinions to support this hyperbole.

On page 8 of the Appendix plaintiffs state:

> there is a 15% to 100% chance that the resulting Shingles rash contains both Oka and wild strains, which Plaintiffs experts will opine was caused by the vaccine strain, which is based on widely accepted principles of immunosenescence that the parties agree upon.

The 15% to 100% chance referenced above says nothing about the specific causation of shingles in any individual plaintiff. These cases will not be decided on general probabilities. The relevance of immunosenescence in establishing specific causation as opposed simply to general probabilities in an older population is not explained.

Plaintiffs spend significant time in their briefs expounding on the issue of general causation, that is, that Zostavax can cause shingles. This focus misses the mark. The issue here is not whether Zostavax can cause shingles as a matter of medical science. General causation by itself as noted above will never be enough for plaintiffs to prevail. Plaintiffs must go further. They must alternatively prove that Zostavax and not the wild-type virus caused each of them to contract shingles.

The court's Lone Pine order was designed merely to require each plaintiff to come forward with prima facie

evidence, either through laboratory reports or other records, that can support the claim that Zostavax caused his or her shingles rather than the wild-type virus. Despite unsupported assertions on the part of plaintiffs, they cannot debunk the premise of that order.

This court, as noted above, has now presided over the MDL for over four years. There has been extensive discovery and a more than sufficient opportunity for plaintiffs to produce any prima facie evidence of specific causation in the Group A cases. The plaintiffs failed with their expert Dr. Poznansky in the five Group A bellwether cases and have produced no relevant evidence even in the face of the subsequent Lone Pine order. If plaintiffs had prima facie proof of specific causation, common sense dictates that it would have surfaced by now.

Our Court of Appeals has emphasized that district courts presiding over an MDL must be "granted significant latitude to manage their dockets and to mitigate 'potential burdens on the defendants and court.'" Hamer v. LivaNova Deutschland GmbH, 994 F.3d 173, 178 (3d Cir. 2021) (citation omitted). The Court has explained that "management orders are essential tools in helping the court weed out non-meritorious . . . claims." Id. In In re Asbestos Prod. Liab. Litig. (No. VI), 718 F.3d 236, 248 (3d Cir. 2013), an MDL, the Court

affirmed dismissal of actions for failure to comply with a Lone Pine order which required production of medical evidence.

Finally, this court must consider relevant factors under Poulis v. State Farm Fire & Cas. Co., 747 F.2d 863 (3d Cir. 1984), before any dismissal of these actions as Merck requests.[5] As these actions are part of an MDL, the court considers Poulis in the context of Hamer and In re Asbestos. Not all factors in Poulis need be satisfied to sustain a dismissal. In re Asbestos, 718 F.3d at 246. The court agrees that the plaintiffs here have not acted willfully or in bad faith insofar as they are unable to produce nonexistent PCR tests. That, however, is not the full story. Plaintiffs still insist in opposition to defendants' motion to dismiss that they have expert evidence to support the required differential analysis that Zostavax and not the wild-type virus caused shingles in all the outstanding cases. Plaintiffs do so even though they have not divulged any of this evidence to the court and know that undisputed evidence exists to the contrary. This is not good faith.

5. The Poulis factors are "(1) the extent of the party's personal responsibility; (2) prejudice to the adversary; (3) a history of dilatoriness; (4) whether the conduct of the party was willful or in bad faith; (5) the effectiveness of sanctions other than dismissal; and (6) the meritoriousness of the claim or defense." In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig., 687 F. App'x 210, 213 (3d Cir. 2017) (citing Poulis, 747 F.2d at 868-70).

Furthermore, it cannot be denied that after more than four years there has been significant delay with the Group A cases. These cases have remained at a standstill since the dismissal of the five Group A bellwether cases on December 1, 2021. There is nothing before the court to indicate that the Group A plaintiffs can ever succeed on the merits. Continuing to carry these cases on the docket of MDL 2848 is severely prejudicial to Merck under the circumstances to say nothing of the added administrative burden to this court as it seeks to move this MDL forward. There is no effective sanction other than dismissal.

Accordingly, the court will grant the motion of Merck under Rule 41(b) to dismiss the 1,189 Group A cases identified in Appendix A in which plaintiffs claim that the Zostavax vaccine caused them to suffer from shingles.[6]

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6. At oral argument on the pending motion to dismiss, plaintiffs for the first time argued that their cases should not be dismissed without an analysis of the applicable underlying substantive state law on causation for each case. This argument was not made in the briefing in opposition to Merck's motion for the Lone Pine order or in opposition to Merck's motion to dismiss. This argument is thus waived. E.g., N. Penn Towns, LP v. Concert Golf Partners, LLC, 554 F. Supp. 3d 665, 696 n.10 (E.D. Pa. 2021). Even if state law rather than federal evidence rules apply, plaintiffs have not shown that any state does not require proof of specific causation by a medical expert or that proof of specific causation through a medical expert in any state could be established here without a PCR test. In addition, plaintiffs' speculation about further advances in medicine in detecting causation so as to avoid dismissal is totally without merit.